

EXHIBIT 15

**EXPERT REPORT
DAVID KESSLER, M.D.**

PART A: QUALIFICATIONS AND SCOPE

I. QUALIFICATIONS

1. My name is David A. Kessler, M.D. I received my M.D. degree from Harvard Medical School in 1979 and my J.D. degree from the University of Chicago Law School in 1978.

2. I did my pediatrics training at Johns Hopkins Hospital.

3. I was appointed in 1990 by President George H. W. Bush as Commissioner of the United States Food and Drug Administration (“FDA”) and was confirmed by the United States Senate. I also served in that position under President William Jefferson Clinton until February 1997.

4. I have taught food and drug law at Columbia University Law School, and I have testified many times before the United States Congress on food, drug, and consumer protection issues under federal and state law. Over the last thirty years, I have published numerous articles in legal, medical, and scientific journals on the federal regulation of food, drugs, and medical devices. I have had special training in pharmacoepidemiology at Johns Hopkins Hospital. My resume, including a list of my published books and articles, is included in Appendix A. A list of cases in which I have appeared as a witness, and documentation of my expert witness fee, is attached as Appendix B.

5. As Commissioner, I had ultimate responsibility for implementing and enforcing the United States Food, Drug, and Cosmetic Act. I was responsible for overseeing five Centers within the FDA. They included, among others, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research. In addition to those duties, I placed high priority on getting promising therapies for serious and life-threatening diseases to patients as quickly as possible. During my tenure as Commissioner, the FDA announced a number of new programs including: the regulation of the

marketing and sale of tobacco products to children; nutrition labeling for food; user fees for drugs and biologics; preventive controls to improve food safety; measures to strengthen the nation's blood supply; and the MEDWatch program for reporting adverse events and product problems involving both drugs and devices. I created an Office of Criminal Investigation within the Agency to investigate suspected criminal violations of the Food, Drug, and Cosmetic Act, FDA regulations, and other related laws. I worked closely with and was ultimately responsible for the FDA's Division of Drug Marketing, Advertising and Communications. I have published articles on drug promotion and marketing practices.¹ I have likewise written extensively on the issue of addiction and have been heavily involved in the science of addiction since investigating and regulating nicotine-containing tobacco products while at FDA.

6. I am a senior advisor to TPG Capital, a leading global private equity firm, which owns pharmaceutical and biomedical companies. I previously served on the board of Aptalis Pharma and Tokai Pharmaceuticals, and I currently serve on the board of the medical device and biologics company Immucor, Inc. In these advisory and fiduciary capacities, I have advised companies on the standards and duties of care in the pharmaceutical and medical device industry. I also previously chaired the compliance committees of Aptalis, and I currently chair the quality committee of Immucor, which involves ensuring compliance with FDA laws and requirements.

7. Listed in Appendix C are documents I accessed independently from various sources, including but not limited to the FDA's website and the relevant discovery databases, and documents that have been provided to me by counsel. At my request, Appendix C was prepared

¹ These include: Kessler, D. (1990). The federal regulation of prescription drug advertising and promotion. JAMA 264:2409-15; Kessler, D. (1991). Drug promotion and scientific exchange. The role of the clinical investigator. N Engl J Med 325:201-3; Kessler, D. (1991). Communicating with patients about their medications. N Engl J Med 325:1650-2; Kessler, D. Therapeutic-class wars--drug promotion in a competitive marketplace. N Engl J Med 331:1350-3; Kessler, D. (2007). Direct-to-consumer advertising: is it too late to manage the risks? Ann Fam Med 5:4-5.

by counsel. Based on my review of those documents and my training and experience, I have a number of opinions that are detailed below.

8. The causes of action in this litigation include: public nuisance; negligence; common law fraud; civil conspiracy; violation of the Racketeer Influenced and Corrupt Organizations (“RICO”) Act; violation of consumer protection laws; and unjust enrichment.

9. It is my understanding that the plaintiffs include: County of Cuyahoga and County of Summit.

10. Likewise, it is my understanding that the defendants in this action are as follows: Actavis LLC, Actavis Pharma, Inc., Allergan Finance LLC, Allergan PLC, AmerisourceBergen Drug Corporation, ANDA, Inc., Cardinal Health, Inc., Cephalon, Inc., CVS Indiana, LLC, CVS Rx Services, Inc., Discount Drug Mart, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., H.D. Smith Holding Company, H.D. Smith Holding Company (County of Cuyahoga Only), H.D. Smith Holdings LLC, H.D. Smith Holdings, LLC (County of Cuyahoga Only), H.D. Smith LLC d/b/a H.D. Smith, H.D. Smith, LLC d/b/a H.D. Smith (County Of Cuyahoga Only), HBC Service Company, Health Mart Systems, Inc., Health Mart Systems, Inc. (County of Cuyahoga only), Henry Schein Medical Systems, Inc., Henry Schein Medical Systems, Inc. (County of Summit only), Henry Schein, Inc., Henry Schein, Inc. (County of Summit only), Insys Therapeutics, Inc., Janssen Pharmaceuticals, Inc., Johnson & Johnson, Mallinckrodt LLC, Mallinckrodt PLC, McKesson Corporation, Miami-Luken, Inc., Noramco, Inc., Par Pharmaceutical Companies, Inc., Par Pharmaceutical, Inc., Prescription Supply, Inc., Purdue Pharma, Inc., Purdue Pharma, L.P., Rite Aid of Maryland, Inc. d/b/a Rite-Aid Mid-Atlantic Customer Support Center, Inc., Specgx LLC, Teva Pharmaceutical Industries, Ltd., Teva

Pharmaceuticals USA, Inc., The Purdue Frederick Company, Inc., Walgreen Co., Walgreen Eastern Co., Walmart Inc., Watson Laboratories, Inc.

11. The opioid products discussed in this report include: OxyContin (Purdue), OxyContin Reformulated (Purdue), MS Contin (Purdue), Opana ER (Endo), Opana ER reformulated (Endo), Percocet (Endo), Duragesic (Janssen), Nucynta IR (Janssen), Nucynta ER (Janssen), Actiq (Teva), Fentora (Teva), Kadian (Actavis), Exalgo (Mallinckrodt), Xartemis ER (Mallinckrodt), and generic OxyContin (Mallinckrodt).

II. SCOPE

12. I have been asked by counsel for the plaintiffs to discuss drug sponsor obligations under standards provided under United States food and drug laws, regulations, guidances, and industry practice as they pertain to prescription opioids, and to discuss the purposes of those obligations and standards and the effect, if any, that any departures from those standards would be expected to have on the use, misuse and abuse of prescription opioids during the past two decades or so. I have also been asked to review the discovery records of specified defendant opioid manufacturers² for the purpose of formulating an opinion as to whether any one or more of those manufacturers departed from accepted drug regulatory standards and, if so, to describe how.³

² As used throughout this report, the term "manufacturer" refers to a sponsor of a drug.

³ The following Schedules are attached to this Report:

Schedule 1 contains general information about the drugs that are the subject of this Report.

Schedule 2 contains the approval dates of various dosages of the drugs that are the subject of this Report.

Schedule 3 contains a Morphine Milligram Equivalent (MME) conversion table.

Schedule 4 contains definitions of addiction and related terms.

Schedule 5 contains a list of Defendants and Plaintiffs in this MDL.

Schedule 6 contains relevant communications from FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC).

Schedule 7 contains relevant FDA Advisory Committee materials.

Schedule 8 contains IMS sales data for the drugs that are the subject of this Report. I understand from counsel that this Schedule has been prepared by Greylock McKinnon Associates.

Schedule 9 contains FDA's Risk Evaluation and Mitigation Strategies (REMS) requirements for oral opioids.

473.2. Factory sales of Actiq increased from \$1.8 million in the first quarter of 2000 to \$30.1 million by the second quarter of 2002.¹⁰⁰⁸ By the third quarter of 2004 factory sales had increased to over \$107 million.¹⁰⁰⁹

473.3. Actiq's sales continued to grow with sales totaling \$590.7 million in 2006.¹⁰¹⁰ By 2006 the price had increased to approximately \$1,863.¹⁰¹¹

473.4. The number of Actiq prescribers also increased during in this same time period from 26,200 prescribers in 2000 to 471,068 by 2005.¹⁰¹²

474. In my opinion, Teva marketed Actiq for non-cancer pain, an indication that lacked substantial evidence to support safety.

3. Teva Failed to Comply with its Risk Management Strategies in Marketing Actiq

475. FDA considered the Actiq RiskMap an “integral part of the approved NDA...and is an essential component of the terms of this NDA’s approval by FDA for marketing...”¹⁰¹³ The purpose of the RiskMap was “to ensure the safe use” of Actiq, and “[r]edundancy of the program elements is one measure used to strengthen the effectiveness of the [RiskMap].”¹⁰¹⁴

476. The FDA-mandated RiskMap required the dissemination of “key messages” on “Proper Patient Selection,” including “Actiq is specifically indicated solely for the treatment of

¹⁰⁰⁶ TEVA_CHI_00043010 at 11.

¹⁰⁰⁷ TEVA_CHI_00043010 at 11.

¹⁰⁰⁸ TEVA_CHI_00042882 at 6.

¹⁰⁰⁹ TEVA_CHI_00043010 at 9.

¹⁰¹⁰ TEVA_CHI_00043963 at 45.

¹⁰¹¹ TEVA_CHI_00043963 at 46.

¹⁰¹² TEVA_CHI_00043963 at 47.

¹⁰¹³ Actiq Approval Letter, November 4, 1998
https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf at 2.

¹⁰¹⁴ TEVA_MDL-A-03272088 at 5.

“Other pain” was the most frequently treated underlying condition (27%) followed by back pain (20%) and other diagnosis (20%).¹⁰²⁸

491. The same July 2008 marketing presentation reported that in July 2007 pain specialists were writing the most Fentora prescriptions (49%), followed by primary care physicians (22%), and other physicians (20%).¹⁰²⁹ Oncologists wrote only 3% of the prescriptions.¹⁰³⁰ In May 2008, there was a slight decrease in prescribing pain specialists (47%), and an increase in primary care prescribers (23%).¹⁰³¹

492. From September 2007 to December 2008, pain specialists continued to write the most Fentora prescriptions (44%), followed by primary care physicians (21%).¹⁰³² Oncologists continued to rarely write Fentora prescriptions (3%).¹⁰³³ During this time there was an overall decrease in the number of pain specialists prescribing Fentora on a monthly basis.¹⁰³⁴

493. In my opinion, Teva promoted Fentora for non-malignant pain, which lacked substantial evidence to support safety.

¹⁰²⁸ TEVA_MDL_A_01500140 at 41.

¹⁰²⁹ TEVA_MDL_A_01500140 at 59.

¹⁰³⁰ TEVA_MDL_A_01500140 at 59.

¹⁰³¹ TEVA_MDL_A_01500140 at 60.

¹⁰³² TEVA_MDL_A_00398245 at 31.

¹⁰³³ TEVA_MDL_A_00398245 at 31.

¹⁰³⁴ TEVA_MDL_A_00398245 at 31.